IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Rader

Application No.: 10/591,923 | Confirmation No.:5393

Filed: June 21, 2007 | Art Unit: 1614

For: Methods for Treating Disorders or Diseases Associated with Hyperlipidemia | Examiner: K. Weddington

DECLARATION OF WILLIAM SASIELA, PH.D., UNDER 37 CFR 1.132

I, William Sasiela, hereby declare as follows:

1. I am Executive Vice President and Chief Medical Officer at Aegerion Pharmaceuticals, Inc, the licensee of the above referenced Patent Application.

2. I have extensive experience in lipid metabolism and therapies for atherosclerosis and related diseases, as evidenced by the copy of my curriculum vitae attached as Exhibit A.

3. I have read and understood the Application, including the currently-pending claims, and the cited prior art patents of Biller and Gregg.

4. I make this declaration in order to provide my scientific opinions and facts known to me which may be of assistance in the examination of the Application.

5. I understand that, prior to the claimed method for treating hyperlipidemia or hypercholesterolemia that includes stepwise increasing dose levels, the claimed MTP inhibitor had been the subject of human clinical trials for the treatment of hypercholesterolemia, where the MTP inhibitor was administered at a *constant* dose level of 25 mg/day or above. Because of adverse events that included clinically significant gastrointestinal steatorrhea and statistically significant hepatobiliary (elevation of liver function tests and fatty liver), the clinical trials and further development of the drug were discontinued, despite significant reduction in patient cholesterol.

6. To my knowledge, few medications for treatment of hyperlipidemia or hypercholesterolemia are administered to patients with stepwise increasing dose levels to minimize side effects. For example, manufacturers of statins, the world's largest category of lipid lowering drugs, have not employed, to my knowledge, step wise increasing doses (titration) in order to minimize side effects that would otherwise be observed at high doses. Ezetimibe (Zetia®), another type of lipid lowering drug, was developed and received FDA approval at a single dose level.

7. I believe that the claimed method for treating hyperlipidemia or hypercholesterolemia that includes stepwise increasing dose levels as recited in claim 1 would have not been obvious to a person skilled in the art at the time of the invention on the basis of any teaching of the Biller or Gregg patents and/or on the basis of general knowledge of those skilled in the art. I note that previous developers of this MTP inhibitor, who appear to have invested much thought and effort on the research and previous clinical trial did not arrive at a solution to the adverse events shown in patients at constant level dosing.

8. My colleagues and I have supervised Phase I, II, and III clinical trials, including Phase II randomized, double-blind human clinical trials, to assess the effectiveness and rate of adverse events of the instantly claimed methods of treating hyperlipidemia or hypercholesterolemia. I present below a summary of findings obtained using the claimed method.

9. Patients were administered low doses of the claimed MTP inhibitor (as pictorially represented in pending claim 1). Patients in study 1 were administered a *constant* level of 10 mg of the MTP inhibitor daily for 12 weeks. Patients in study 2, which included two arms, 2A, and 2B, were *first* administered 5 mg of the MTP inhibitor for 4 weeks, *then* administered 7.5 mg of the MTP inhibitor for 4 weeks, and *then* administered 10 mg of the MTP inhibitor for 4 more weeks. The results are depicted in Table A:

Study (Total N)	Study	Study Duration	Rate of GI Discontinuations	Rate of GI adverse events	Rate of Diarrhea
1 (260)	10 mg	12 weeks	9/35	30/35 (85.7%)	23/35 (65.7%)
2A (85)	5→10 mg	12 weeks	2/28	18/28 (64.3%)	11/28 (39.3%)
2B (85)	5→10 mg + 10 mg eze	12 weeks	1/28	12/28 (42.9%)	10/28 (35.7%)
3 (25)**	5→60 mg	78 weeks	3/25	12/21 (57.1%)	9/21 (42.9%)

**Adverse event rates based on analysis of 21 treated patients

Table A

10. Patients in study 2A had a dramatic difference in the rate of patient discontinuation rate due to gastrointestinal (GI) effects, and in the rate of GI adverse events and diarrhea, as compared to study 1.

11. Patients in study 2B, like study 2A, were also first administered 5 mg of the MTP inhibitor for 4 weeks, *then* administered 7.5 mg of the MTP inhibitor for 4 weeks, and *then* administered 10 mg of the MTP inhibitor for 4 more weeks. These patients were additionally administered ezetimibe (10 mg daily, at a constant dosage level). Surprisingly, patients administered both ezetimibe and the claimed MTP inhibitor, starting at a 5 mg dose level for four weeks, also had significantly decreased GI adverse events and diarrhea, even compared to patients administered constant level of 10 mg of the MTP inhibitor *alone*.

12. Patients in study 3 suffer from homozygous familial hypercholesterolemia (hoFH), and were first administered 5 mg of the same MTP inhibitor used in study 1 and 2 for four weeks, then administered 10 mg of the MTP inhibitor for four weeks, then administered 20 mg of the MTP inhibitor for four weeks, then 40 mg of the MTP inhibitor for four weeks, then 60 mg of the MTP inhibitor, or to the highest tolerated dose.

13. Surprisingly, the patients in study 3, *initially administered 5 mg of MTP inhibitor*, and subsequently administered up to 60 mg of the MTP inhibitor, after escalation of dose levels to a mean dose level of 44 mg/day, show a lower rate of GI adverse events and diarrhea even as compared to the patients of study 1, who were administered a *constant level* of 10 mg of the MTP inhibitor.

14. I believe that the reduced incidence of GI adverse events and diarrhea in the patient groups 2 and 3, as indicated in Table A, is an unexpected result of the claimed method, especially as compared to administration of the same MTP inhibitor without escalating doses.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Dated: April 8, 2010

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EXECUTIVE PROFILE

Strong Phase II-Phase IV research background in the metabolic and cardiovascular therapeutic areas with particular interests and experience in lipids, atherosclerosis, diabetes and obesity. Research experience has covered many facets of development ranging phase II studies for small, orphan populations to multithousand, multiyear phase IIIb-IV CV event trials. Brings extensive experience in medical-marketing issues surrounding both US and Worldwide pharmaceutical markets in the metabolic and CV therapeutic areas. Strong track record of managing and creating cross-functional teams. Experience in evaluating strategic opportunities with individual compounds and within overall internal development programs. Noted for excellent speaking and communication abilities.

PROFESSIONAL EXPERIENCE

Aegerion Pharmaceuticals, Inc., Bridgewater, NJ **2005-Present**

Executive Vice President & Chief Medical Officer

As the third employee to join the newly formed biotech company, had the responsibility for overall development strategy and programs, design of clinical trials and formation of internal clinical development team. Had overall responsibility for all facets of product development including clinical trials, manufacturing and regulatory functions.

- Development strategy for AEGR-733 and AEGR-427 for hyperlipidemia including phase 2 and phase 3 clinical trials as well as necessary preclinical and pharmacokinetic studies.
- Led team that successfully designed and executed 6 phase 2/3 clinical trials and 11 preclinical studies for AEGR-733.
- Creation of teams and hiring of personnel to support all developmental activities including clinical operations, regulatory affairs and manufacturing.
- Development and execution of all meetings relating to the Aegerion Scientific Advisory Board.
- Member of the Aegerion Executive team with participation and presentation at all Aegerion Board of Director meetings.
- Significant role in all private and public financing activities.
- Evaluation of all potential in-licensing candidates including compounds in the areas of type 2 diabetes (e.g. DDP-IV, long-acting insulin), dyslipidemia and cardiovascular disease.

Pfizer/Parke-Davis, New York, NY/Morris Plains, NJ **1996-2005**

Senior Clinical Director/Worldwide Team Leader *2003-2005*

Led Worldwide Medical Teams for Lipitor and the Atherosclerosis Development at Pfizer's NY headquarters. The latter group focused on developmental programs for in the area of lipids and atherosclerosis and included torcetrapib/atorvastatin program and the compounds that were acquired via the Esperion acquisition. During this period, worldwide revenues for Lipitor grew from $7.9 B (2002) to $12.2 B (2005). Also within this role, was member of cross-functional team that drove strategy for the entire CVME franchise within Pfizer from discovery to commercialization.

- Led the overall medical program and medical/marketing strategy for Lipitor worldwide including the clinical trial program, sNDAs and other regulatory responses, country/regional medical/marketing initiatives.
- Ensured alignment and appropriate roll-out of medical strategies between NYHQ, US and other key regions.
- Played integral role in the development of the extensive phase 3 program and proposed labeling for torcetrapib/atorvastatin
- Led efforts around lifecycle management for an established product (Lipitor) and an emerging product (torcetrapib/atorvastatin)
- Worked with Pfizer L&D team to identify and evaluate potential in-licensing candidates. Performed technical due diligence on compounds of interest.
- Contributed to overall PFE strategy in CVME through activity in Therapeutic Area Strategy Teams. In particular, led efforts around identification and prioritization of enabling strategies for all CVME development areas.
- Led a cross-functional team to develop strategies for validation of atherosclerosis imaging techniques and plasma biomarkers.
- Managed multimillion dollar annual budgets for both the Lipitor and Atherosclerosis Development programs.

Clinical Director/Lipitor Medical Team *2000-2003*

As a member of the Lipitor Medical Team, directly oversaw key clinical trials and medical-marketing strategy activities as well as contributed to the overall medical and marketing strategies for the brand.

- Directly managed a number of phase IIIb/IV trials such as MIRACL, REVERSAL, BELLES and SPARCL including management of clinical study teams and budgets
- Led medical-marketing initiative to handle emerging scientific issues and competitive threats including new market entrants, HDL-C and novel pleiotropic effects of statins.

- Led the organization and management of the 2002 Atorvastatin Global Investigators Meeting (1000+ Global OL attendees)
- Initiated, developed and managed a global research awards program focused on HDL-C (annual budget of $1.5-2.0 MM)
- Rolled out the results of first large scale CV event reduction data (ASCOT trial) in the U.S. including the sNDA application and marketing materials.
- Oversaw development of materials for training and updating of US and Worldwide Lipitor field salesforce
- Independently and in conjunction with field medical colleagues, developed and maintained relationships with KOLs in lipids and atherosclerosis
- Developed strategies for and gave presentations to large managed care and governmental organizations

Medical Liaison Specialist *1998-2000*

In addition to maintaining regional field medical activities as described in the medical liaison position, chaired the Diabetes Therapeutic Strategy Group (DTSG) within the Parke-Davis medical liaison team. As chair of the DTSG, led or coordinated a number of activities including:

- Coordination of medical and marketing strategies for diabetes/troglitazone between the Parke-Davis HQ teams and the US medical liaison team.
- Development and management of knowledge database for the US medical liaison team in relation to diabetes which included an extensive, organized slide database and a medical literature updates.
- An internship rotation within the Parke-Davis HQ diabetes medical team which included active involvement in analysis of completed clinical trials and initiation of a new clinical trial.
- Training of new medical liaisons in regards to type 2 diabetes, insulin resistance and troglitazone.
- Involvement in national CME programs related to diabetes.

Medical Liaison/Sr. Medical Liaison *1996-1998*

A member of the first group of medical liaisons at Parke-Davis. At various times covered some or all of the regions including Delaware, Maryland, Washington DC, Virginia and West Virginia. Responsible for regional medical coverage of all commercial and phase 3 products/programs at Parke-Davis which included hyperlipidemia (Lipitor), type 2 diabetes (Rezulin), hypertension (Accupril), the CNS areas of epilepsy, neuropathic pain, depression (Neurontin, Celexa and Dilantin).

- Understand and develop relationships with key researchers and opinion leaders in the relevant therapeutic areas.
- Identification of phase II-IV research sites for HQ medical teams.

- Facilitate independent research studies between regional opinion leaders and headquarters medical teams.
- Act as a local product expert for regional physicians through one-on-one meetings and group presentations.
- Provide therapeutic area and product training and support to the local sales representatives and managers.

POST-DOCTORAL EDUCATION AND EXPERIENCE

High School Science Instructor – Southern Vance High School, Henderson, NC. 1995-1996.
Taught Physical Science, Biology and Anatomy and Physiology
Voted Best Lecturer by the student body.

Post-Doctoral Fellowship – University of North Carolina School of Medicine, Chapel Hill, NC. 1994-1995.
Kathy Pryzwansky, Advisor
Research project focused on the role of cGMP and its main intracellular receptor, cGMP-dependent protein kinase (G-kinase), in human monocytes. Specifically, worked to characterize the G-kinase present in human monocytes and determine the role of cGMP and G-kinase in the adhesion of human monocytes to serum-coated substratum.

PRE-DOCTORAL EDUCATION

Ph.D. - University of South Carolina School of Medicine, Columbia, South Carolina
Experimental Pathology, 1994. Stanley Fowler, Advisor.
Research into the biological role that macrophage-derived foam cells play in the initiation and progression of atherosclerotic lesions.

B.S. - Virginia Polytechnic Institute and State University, Blacksburg, Virginia
Biochemistry (Minors in Biology and Chemistry), 1987.

PUBLICATIONS

Papers and/or chapters:

Samaha F, McKenney J, Bloedon L, **Sasiela W**, and Rader, D. Inhibition of Microsomal Triglyceride Transfer Protein Alone or in Combination with Ezetimibe in Patients with Moderate Hypercholesterolemia. Nature Clin Prac Cardiovasc Med. 2008 Aug;5(8):497-505.

Libby P, **Sasiela W**. Plaque stabilization: Can we turn theory into evidence?
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Pharmacogenomics J. 2005;5(6):352-8.

Olsson AG, Schwartz GG, Szarek M, **Sasiela WJ**, Ezekowitz MD, Ganz P, Oliver MF, Water D, Zeiher A. High-density lipoprotein, but not low-density lipoprotein cholesterol levels influence short-term prognosis after acute coronary syndrome: results from the MIRACL trial. Eur Heart J. 2005 Mar 11

Nissen SE, Tuzcu EM, Schoenhagen P, Crowe T, **Sasiela WJ**, Tsai J, Orazem J, Magorien RD, O'Shaughnessy C, Ganz P; Reversal of Atherosclerosis with Aggressive Lipid Lowering (REVERSAL) Investigators. Statin therapy, LDL cholesterol, C-reactive protein, and coronary artery disease. N Engl J Med. 2005 Jan 6;352(1):29-38.

Tsimikas S, Witztum JL, Miller ER, **Sasiela WJ**, Szarek M, Olsson AG, Schwartz GG; Myocardial Ischemia Reduction with Aggressive Cholesterol Lowering (MIRACL) Study Investigators. High-dose atorvastatin reduces total plasma levels of oxidized phospholipids and immune complexes present on apolipoprotein B-100 in patients with acute coronary syndromes in the MIRACL trial. Circulation. 2004 Sep 14;110(11):1406-12. Epub 2004 Sep 07.

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Kinlay S, Schwartz GG, Olsson AG, Rifai N, Leslie SJ, **Sasiela WJ**, Szarek M, Libby P, Ganz P; Myocardial Ischemia Reduction with Aggressive Cholesterol Lowering Study Investigators. High-dose atorvastatin enhances the decline in inflammatory markers in patients with acute coronary syndromes in the MIRACL study. Circulation. 2003 Sep 30;108(13):1560-6. Epub 2003 Sep 15.

Fowler, S.D., Gasque-Carter, P.D., Patillo-Adkisson,E., **Sasiela, WJ** and Xenachis, D.N. Cellular models of atherosclerosis in the young. Chapter 5: Hyperlipidemia in Childhood and the Development of Atherosclerosis. Ann. N.Y.Acad. Sci.,623:60-69, 1991.

Abstracts and presentations:

Bilheimer J, Crowley D, **Sasiela W**, Rader DJ. Menhaden Oil Ameliorates the Steatosis Caused by the Inhibition of Microsomal Triglyceride Transfer Protein. Presentation at the Arteriosclerosis, Thrombosis and Vascular Biology Meeting; April 29 – May 1, 2009.

Samaha F, McKenney J, Bloedon L, **Sasiela WJ**, Rader D. Efficacy and Safety of the MTP-Inhibitor, AEGR-733, as Immunotherapy and in Combination with Ezetimibe. Presentation at the XVI International Symposium on Drugs Affecting Lipid Metabolism; October 4–7, 2007; New York, NY, USA.

Samaha F, McKenney J, Bloedon L, **Sasiela WJ**, Rader D. MTP-Inhibitor, AEGR-733, Reduces Body Weight in Patients with Hypercholesterolemia. Presentation at the XVI International Symposium on Drugs Affecting Lipid Metabolism; October 4–7, 2007; New York, NY, USA.

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Samaha FF, McKenney J, Bloedon L, **Sasiela WJ**, Rader DJ. Efficacy and Safety of the MTP-inhibitor, AEGR-733, as Monotherapy and in Combination with Ezetimibe. *Circulation.* 2006;114:II_289.

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Sasiela WJ, Silbershatz H, Szarek M. Analysis of the Renal Safety of Atorvastatin in a Broad Spectrum of Patients with Dyslipidemia. Poster presentation at the 74th Congress of the

European Atherosclerosis Society; April 17-20, 2004; Seville, Spain.

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Copley, S.D., Frank, E., Koch, T.H., Kirsch W.M., Hunsaker, R., Van Buskirk, J., Nehlsen-Cannarella, S., Gasque-Carter, P.D., **Sasiela, WJ** and Fowler, S.D. Aminomalonic acid (AMA) detected in selected proeins from granuloma foam cells by gas chromatography/mass spectrometry. FASEB J. 5:A533, 1991.

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Gasque-Carter, P.D., **Sasiela, WJ** and Fowler, S.D. Biochemical and flow cytometric analysis of granuloma foam cell subpopulations. J. Cell Biol. 111:309a, 1990.